

101. (New) A recombinant host cell comprising the nucleic acid molecule of claim 94 operably associated with a regulatory element that controls expression of said nucleic acid molecule.

102. (New) A method of producing a polypeptide encoded by the nucleic acid molecule of claim 94, comprising:

- (a) culturing a host cell comprising said nucleic acid molecule under conditions suitable to produce said polypeptide; and
- (b) recovering said polypeptide from the culture.

103. (New) A composition comprising the nucleic acid molecule of claim 94 and a pharmaceutically acceptable carrier.--

#### REMARKS

#### Amendments to the Sequence Listing/Statements Under 37 C.F.R. § 1.825(a) and (b)

The Sequence Listing has been replaced with a Substitute Sequence Listing to correct a minor editorial error, and to bring the Sequence Listing into conformity with the specification and the Figures. More specifically, the original Sequence Listing did not recite the complete translation of SEQ ID NO:1 into SEQ ID NO:2. The encoded polypeptide sequence was inadvertently terminated at amino acid residue position 316, instead of amino acid residue 336 just before the stop codon, as shown in Figure 1B and as noted in the specification in Table 1 at page 8. Similarly, the original Sequence Listing did not recite the complete translation of SEQ ID NO:5 into SEQ ID NO:6. The encoded polypeptide sequence was inadvertently terminate at amino acid residue position 541 instead of amino acid residue 574 just before the stop codon as shown in Figure 3B and as noted in the specification in Table 1 at page 8. The complete translations of SEQ ID NOS:1 and 3, and the corresponding complete amino acid sequences for the polypeptides of SEQ ID NOS:2 and 4, are provided in the Substitute Sequence Listing submitted herewith.

In accordance with 37 C.F.R. § 1.825(a), the undersigned attorney for Applicants hereby states that the amendments to the Sequence Listing contained in the Substitute Sequence Listing submitted herewith are completely supported in the specification as originally filed (at Figures 1B and 3B and in Table 1 at page 8) and no new matter has been introduced.

In accordance with 37 C.F.R. § 1.825(b), the undersigned attorney for Applicants hereby states that the information contained in the paper copy of the Substitute Sequence Listing submitted herewith is identical to the information contained in the computer readable form of the Substitute Sequence Listing submitted herewith.

### **Amendments to the Specification**

The specification has been amended at page 14 to insert text from prior Application No. 60/070,875, which is incorporated by reference into the instant application (see page 1, lines 3-6). The inserted text is identical to the text as it appeared in prior Application No. 60/070,875 at page 31, line 10 to page 32, line 10, as stated in the Declaration Under 37 C.F.R. 1.68 and M.P.E.P. 608.01(p), submitted herewith, and no new matter has been introduced.

### **Amendments to the Claims**

Claims 21-103 are pending in view of the amendment above.

Claims 1-20 have been canceled with out prejudice, and Applicants reserve the right to pursue the subject matter of these claims in this or continuing applications.

Claims 21-103 have been added to more particularly point out and distinctly claim the subject matter Applicants regard as the invention. Support for newly added claims is found throughout the specification as filed, and no new matter has been introduced.

More particularly, support for new claims can be found in the specification as follows: Table 1 at page 8; Figures 3A-C, Figures 4A-B; page 21, lines 15-22 (lack of an N-terminal methionine); page 3, line 6 (complementary sequences); pages 18-19 (heterologous polypeptides including Fc domains); pages 20-21 (vectors, host cells, and methods of production); Example 13 at pages 50-53 (pharmaceutical compositions); and page 12 and the text inserted at page 14 by the amendment above (95% identity and Bestfit).

### **The Claims Are Enabled Under 35 U.S.C. § 112, First Paragraph**

The Examiner has rejected claims 1-5, 7-10, and 15, under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. More specifically, the Examiner contends that the specification is not enabling for nucleotide sequences encoding amino acid sequences of at least 95% identity with the specified amino acids sequences.

More specifically, the Examiner states at page 5 of the Office Action:

Although methods for determining the percent identity are disclosed in the specification, such as the computer program FASTDB, only preferred methods used by the applicant have been disclosed, and accordingly the specification is not limited to the computer program FASTDB. Thus use of "percent" in conjunction with any of the various terms that refer to sequence similarity is a problem since sequence identity between two sequences has no common meaning within the art. The term "percent" can be defined by the algorithm and parameter values set when using the algorithm used to compare the sequences. The scoring of gaps when comparing one sequence to another introduces uncertainty as to the percent of similarity between the two sequences. Therefore, the scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid encoding the amino acid sequences broadly encompassed by the claims due to the significant number of untaught sequences. Therefore, there is no

evidence of record to show that one skilled in the art would be able to practice the invention without an undue amount of experimentation.

In sum, the claims are alleged to be not enabled because the lack of common meaning for the term % identity allegedly requires an undue amount of experimentation to determine whether a given sequence is within the scope of the claims.

Applicants respectfully disagree that a problem exists determining % identity or that any undue experimentation would be required to practice the invention as originally claimed. Nonetheless, Applicants have presented new claims that specify % identity in which the concerns of the Examiner have been addressed. More specifically, new claims 38, 68, 94, and their dependent claims, now specify that the % identity is not determined by "any" method, but by the Bestfit algorithm described in detail at page 12 of the specification by way of the amendment above. Thus, the person of ordinary skill in the art would be able to readily determine whether a given nucleotide sequence has the % identity value specified in the claims. Thus, the specification enables the full scope of the claims and it would not be an undue burden to make and use the claimed nucleic acid molecules. Accordingly, Applicants respectfully request that the rejection under § 112, first paragraph, be withdrawn.

With respect to the references to the C-terminal residues of SEQ ID NOS:2 and 6, Applicants thank the Examiner for noting the discrepancies between the original Sequence Listing and the claims. Applicants note that the Substitute Sequence Listing submitted herewith is consistent with the claims, specification, and figures as originally filed.

In view of the amendments and comments above, Applicants believe that the rejections under 35 U.S.C. § 112, first paragraph, have been overcome and respectfully request that the rejections be withdrawn.

#### **The Claims Are Definite Under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected claims 1-5, 7-10, and 15, under 35 U.S.C. § 112, second paragraph.

The rejection of claim 1 (and its dependent claims), with respect to the references to the C-terminal residues of SEQ ID NOS:2 and 6, as it applies to the new claims, has been obviated by the amendments to these SEQ ID NOS in the Substitute Sequence Listing submitted herewith, as detailed above. Applicants further note that SEQ ID NO:2 is not specified in the new claims.

The rejection of claim 5, with respect the sequence of nucleotides 3-1166 has been obviated cancellation of this claim. Applicants further note that claim 28, which specifies this nucleotide range, properly refers to SEQ ID NO:7.

The rejection of claim 7, with respect to the typographical error, has been obviated in view of the cancellation of this claim.

Thus, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

**VI. Rejections under 35 U.S.C. §§ 102(b) and 103(a)**

The Examiner has rejected claims 1, 2, 3, 5, and 6-10 under 35 U.S.C. § 102(b), and claims 6-10, and 15 under 35 U.S.C. § 103(a), as they relate to SEQ ID NOS:2 and 4.

Applicants note that the subject matter relating to SEQ ID NOS:2 and 4 has been canceled, without prejudice, solely to expedite the prosecution of this application; and Applicants expressly reserve the right to pursue the subject matter of these claims in continuing applications. Thus, the rejections under §§ 102(b) and 103(a) have been obviated in view of the amendments above. Accordingly, Applicants respectfully request that these rejections be withdrawn.

**VIII. Conclusion**

Applicants respectfully request that the amendments and remarks of the present response be entered and made of record in the present application. The application is believed to be in condition for allowance. Early notice to that effect is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution, the undersigned can be reached at the telephone number indicated below. If a fee is required in connection with this paper, please charge Deposit Account No. 08-3425 for the appropriate amount.

Respectfully submitted

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